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NIH, **NIAID Case #12276**

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Re: ***Passive Immunization*: Obfuscating treatment denial of novel viruses (e.g.: Measles (Rubeola), RSV, COVID-19, etc.) versus Paltering promotion for rare, chronic, and terminal conditions (e.g.: CIDP, MS, exophthalmos, psoriasis, collagen vascular disorders, cancer, etc.)**

Dear NIAID Director Dr. Marrazzo and Fellows of the American College of Surgeons:

On April fool's day five years ago, the following interaction aired on CBS Nightly News between Norah O'Donnell and Dr. Anthony Fauci, M.D.[1]:

> O'Donnell N: BREAKING NEWS: Dr. Fauci on the fight against the virus. CBS News 2020 April 1. https://www.facebook.com/CBSEveningNews/videos/norah-odonnell-should-we-be-advising-people-to-wear-masksdr-anthony-fauci-great-/204826050813336/ 2:10 – 2:48
>
> > Norah O'Donnell: With all due respect it does seem like so much of this we're making it up as we go along.
> >
> > Dr. Anthony Fauci: Well, you know you make it up as you go along, Norah, because that's what you know—that's where the war is all about. I don't like to necessarily make that analogy to a war, but if you talk to the generals with experience, you have a plan. But when the bullets start flying, everything becomes a fog, and you have to play it by ear. We do have a good plan. We need to be humble that we don't know all the answers, and we don't know how exactly this is going to turn out.
> >
> > Norah O'Donnell: Dr. Fauci, thank you so very much for your time and expertise.
> >
> > Dr. Anthony Fauci: It's always good to be with you, Norah. Thank you.

On that evening as a practicing General Surgeon, I was grateful that Ms. O'Donnell had hit the nail-on-the-head. I reasoned that possibly now, the medicine-powers-that-were throughout the nation in response to Ms. O'Donnell's insightful truism would develop COVID-19 treatment-reasonableness towards the infected or exposed patients based on a greater than 130 year past

history of early treatment with exogenous antibodies (within 72 – 96 hours) utilizing the *Clinical Immunology* foundational concept of ***Passive Immunization.***[2-4]

Unfortunately, I was wrong!

Since the first misstatement of March 2, 2020, of Leonard Schleifer, M.D., CEO of Regeneron Pharmaceuticals, before President Donald Trump when Dr. Schleifer had euphemistically muddied the concept of ***Passive Immunization*** with his statement of "passive vaccination",[5] there followed over the subsequent four weeks in March 2020, a series of misdirections in U.S. Public Health planning for the impending coronavirus, SARS-CoV-2, COVID-19 American epidemic resultant from the *de facto* denial of the distinction between ***Active Immunization*** and ***Passive Immunization*** of *Clinical Immunology,* including[6-13]:

1. the declaration of the Public Health Emergency[14] (that was renewed 13 times)[15] regarding COVID-19 with suspension of parts of EMTALA (March 13, 2020, and March 18, 2020)[16-18], and the *de facto* abridgment of individual patient's rights to ask for therapeutic exogenous immunoglobulins as early treatment (within 72 hours of diagnosis) of COVID-19 infection under PL-115-176, The Right to Try Act of 2017 [19];

2. the Surgeon General issuing a PSA advising all to avoid hospitals if they were sick from COVID-19 (March 19, 2020)[20];

3. the FDA declaring COVID-19 convalescent plasma as "Investigational" (March 24, 2020)[21] when it was a *biosimilar biologic* to FDA approved immunoglobulins[22] , now and in the past, of ***Passive Immunization*** which has been employed successfully for roughly 150 years—e.g., such as as the two-three week Pasteur treatment immediately after rabies exposure; as convalescent plasma during the Spanish flu epidemic; as an approved postexposure IMIG agent against hepatitis A and measles since 1944 (GamaSTAN) of which its continued successfulness has been reconfirmed over the last 15 years in three separate studies; as RhoGam to prevent Rh-sensitization within 72 hours after pregnancy since 1968; as an immediate post exposure therapy and early-in-the-disease-course in the case of individuals unvaccinated to smallpox during the WHO's war on smallpox during the 1970s; as a methodology of increased survival in solid organ transplantation with IVIG (especially in the pre-transplanted sensitized patient) today, etc.; and

4. the institution by the FDA of *de facto* rationing / restriction of immunotherapeutic ***Passive Immunologic*** treatments based incorrectly on a Chinese epidemiology observational study (February 24, 2020)[23] limiting COVID-19 convalescent plasma (and other treatments) to only those severely affect and then only in the later stages of COVID-19 (during the host immune responses of the cytokine cascade and the bradykinin storm) –that is, only "high-risk-of-dying" / severely diseased individuals INSTEAD OF ALL INDIVIDUALS WITHIN 72 HOURS OF DIAGNOSIS during the viremic phase of the disease (March 24, 2020).[21]

As is stated in the introductions to Book 5[12] and Book 6[13]:

Over the course of the last five years under **NIH NIAID case file # 12276**, I have submitted my concerns regarding our treatment (not just prophylaxis / vaccination) of COVID-19, RSV, and measles to many within the Federal Government, U.S. Medicine, and Academia.[6-13] When one looks at my writings over that time period, they reflect my perceived inherent misdirection of our medical thinking or lack of a unification of therapeutic rationale with regards to *Clinical Immunology*. As a student at Saint Louis University School of Medicine (SLUSOM) during my basic science years, I was exposed to the concept of immunology and its applications in medicine at the time. During my time of medical school (1975-1979), pediatric residency (1979-1981), and general surgery residency (1981-1986), and faculty appointments: SLUSOM: (1986-1996), Loyola University SOM: (1996-2002), San Joaquin General Hospital, Stockton, CA: (2002-2005), and SLUSOM (2006-2022)[24], my initiation into practice of Medicine and Surgery was at the start of the human immunodeficiency virus (HIV / AIDS) pandemic, the development of early techniques of DNA sequencing, and the discovery of the elaboration of DNA by polymerase chain reaction (PCR). Molecular biology concepts were in their infancy compared to that which has progressed throughout my medical career and we know today. Many of the facets of Immunology are today outwardly and apparently divergent in application and implementation in Clinical Medicine from my *de facto* neophytic comprehension forty years ago. ***Clinical*** (therapeutic for the individual patient) ***Immunology*** at the time of my education was foundationally divided into:

> ***Active Immunization*** (**prophylaxis** by vaccination) is the provision of exogenous antigens to the individual to promote the body to produce acutely, specific, endogenous immunoglobulins against the presented antigens with, over roughly two-week course, the production of IgGs with the resultant long-term development of plasma cells that retain the memory of the exogenous antigens for years to come. As the development of plasma memory cells are long-term, vaccination (possibly with boosters) can be for life, e.g.: smallpox (and now M ~~monkey~~ pox), DPT, MMR, polio, RSV, chickenpox, hepatitis B vaccines, etc.
>
> *Versus*
>
> ***Passive Immunization*** (**treatment** by convalescent plasma and sera--and today monoclonal antibodies, etc.) is the provision of exogenous antibodies to the individual to address acutely and immediately with exogenous IgGs to specific antigens of infections, toxins, and envenomations in the individual. While accomplishing an immediate treatment during the early phase (viremia) of the disease, these administered exogenous IgGs will have diminishing effectiveness in the individual's serum over about 2 months as the half-life of these IgGs are about 21 days, e.g.: Pasteur's rabies "vaccine", hyperTet, RhoGam, IVIGs, monoclonal antibodies and antibody cocktails, gammaglobulins, e.g.: GamaSTAN® S/D for measles, anti-bacteria and anti-viral immunoglobulins, and anti-snake and anti-insect venoms, etc.

Thus, while ***Active Immunization*** in the individual is relatively long-lasting and protective in the immunocompetent individual, ***Passive Immunization*** in the unvaccinated, the under-vaccinated, and the immunologically-incompetent individual is a relatively short-lived ($t_{½}$ of IgG is ~21 days)[25], therapeutic biologic timespan that can be a life-saving treatment for exposed or infected individuals when most effectively given shortly (<72 to 96 hours) after exposure or diagnosis. The euphemistic[26] confusion in the

politics of U.S. Medicine today suggests vaccination (***Active Immunization***) as an immediate treatment[27-29]--which it is not.[30-31] The only immediate, always-immediately-available, continually always-updating disease-specific ***Passive Polyclonal Immunological*** sources in infectious diseases are some form of convalescent plasma or sera, gamma globulin, IVIG, IMIG, etc. from a recovered, previously-infected individual, pool of individuals, or immunosensitized individual(s) who previously contracted the disease and survived.[2-4] Throughout *Book 5: Summary Submission to President Joseph Biden on January 18, 2020*[12], is a collection of communications, articles, and analyses regarding the early treatment within 72 hours of diagnosis (phase of viremia) of the coronavirus, SARS-CoV-2, COVID-19 with (1) ***Passive Immunization***, e.g.: Convalescent plasma, monoclonal antibodies, etc. and (2) the antiviral Remdesivir (Veklury). Book 6[13] goes one step further elaborating on the fundamental concepts of ***Active Immunization*** (endogenous immunoglobulins / prophylaxis / vaccination) versus ***Passive Immunization*** (exogenous immunoglobulins / treatment and postexposure prophylaxis) in the context of the present-day (2025), public-health-visible viral infections of measles (*Rubeola*), Respiratory Syncytial Virus (RSV), and coronavirus, SARS-CoV-2, COVID-19.

The fundamental distinctions of *Clinical Immunology*: 1.) **Treatment** with ***Passive Immunization*** and 2.) **Prophylaxis** with ***Active Immunization*** have become confused in the public's eyes. ***Passive Immunization*** has all but been dismissed and forgotten in our seemingly present Machiavellian-like societal mindset[32] consistent with *the end justifies the means* and where the *ad hominem* attack[33-35] has become paramount in our daily politics and media. The fundamental clinical principles of ***Passive Immunization***:

(1) date back to Pasteur and von Behring which today have been discarded in our present approach to the unvaccinated or the immune-incompetent individuals who contract or are exposed to a virus;

(2) has successfully been implemented in the acute, early treatment of bacterial and viral infections, toxins, and envenomations over the last century[2-4]; and

(3) should be the foundational cornerstone in our immunotherapeutic treatment of infectious diseases to all those acutely afflicted with an infectious disease and are immunologically naïve to the disease: unvaccinated, under-vaccinated, or immunocompromised. The administration of exogenous immunoglobulins (IgGs) should not be minimized in their appropriate application and importance as the treatments of infectious diseases especially viruses, e.g: measles (Rubeola), RSV, COVID-19, etc.[13-15]

The eradication of smallpox in the late 1970s is by far and away humanity's greatest success story in dealing with an endemic virus. The World Health Organization (WHO) was ultimately successful through the cooperation of all nations in the identification of every new outbreak in unvaccinated individuals and treating those unvaccinated, exposed contacts synergistically with immediate ***Passive Immunization*** and then subsequently with vaccination (***Active Immunization***).[36-44] Today, the United States is experiencing a resurgence in measles

(Rubeola).[45-50] While there are those that are advocating for MMR immunization (***Active Immunization***) of infants down to 6 months of age[51], the administration of exogenous IgG in the form of IVIG or IMIG specific for measles postexposure with six days [e.g: GamaSTAN – ***Passive Immunization*** **(IMIG)]** has been approved by the FDA since 1944.[52-54] Post-exposure prophylaxis within six days of exposure has been recommended over the last 80 years.[55-68] In three recent studies, exogenous antibodies (IVIG or IMIG) continue to be a successful postexposure prophylactic in measles-exposed, unvaccinated individuals)[69-71]:

> **Results:** In 63 (96.9%) of 65 infants PEP of 65 infants PEP with IVIG was administered. The parents of two infants declined IVIG PEP. None of the infants with IVIG PEP got measles or symptoms suggestive for measles, but both infants who did not receive PEP were infected. Effectiveness of IVIG PEP was calculated to be 99.3% (CI 95%: 88.7-100%). No serious adverse event of IVIG treatment was observed. The investigation on MV-neutralizing antibody capacity showed a geometric mean titer ranging from 10.0 to 12.7 IU/ml, resulting in a 1.57-2.26-fold higher concentration than postulated as minimum level for immunity.
> [Kohlmaier *et.al.:* Effectiveness and safety of an intravenous immune globulin (IVIG) preparation in post-exposure prophylaxis (PEP) against measles in infants. Front. Pediatric Infectious Diseases 2021 December 01; 9: Article 762793][69]

> **Results:** A total of 3409 contacts were identified, of which 208 (6.1%), 274 (8.0%), and 318 (9.3%) met the inclusion criteria for analysis of MMR, IG, and any PEP effectiveness, respectively. Of the contacts included, 44 received MMR PEP and 77 received IG PEP. Effectiveness of MMR PEP was 83.4% (95% confidence interval [CI], 34.4%, 95.8%). No contact who received IG PEP developed measles; effectiveness of IG PEP was 100% (approximated 95% CI, 56.2%, 99.8%). Effectiveness of receiving any PEP (MMR or IG) was 92.9% (95% CI, 56.2%, 99.8%).
> [Arciuolo RJ, *et.al.*: Effectiveness of measles vaccination and immune globulin post-exposure prophylaxis in an outbreak setting—New York City, 2013. Clin Infect Dis 2017 Nov 13; 65(11): 1843-1847. https://academic.oup.com/cid/article/65/11/1843/4210618?login=false][70]

> **Intramuscular immunoglobulin**
> Available evidence and product information was reviewed concerning IMIg, which has previously been recommended by NACI for measles PEP at a dose of 0.25 mL/kg for susceptible pregnant women and infants or 0.5 mL/kg for immunocompromised individuals, or for other susceptible contacts who presented between 72 hours and six days post-exposure. GammaSTAN (10) is the only IMIg preparation in Canada, and it is indicated for use as measles PEP. When effectiveness studies were examined based on the relative anti-measles antibody concentrations in current Ig products, it was apparent that IMIg doses exceeding the CBER Reference Standard with current protein concentrations of 0.442 mL/kg, 0.393 mL/kg or 0.335 mL/kg, would result in 100%, 100% and 83% effectiveness respectively against measles up to two weeks post-injection (9)…
> [Tunis MC, *et al*: Updated NACI recommendations for measles post-exposure prophylaxis. CCDR 2018 September 6; 44(9): 226-230. https://www.canada.ca/content/dam/phac-aspc/documents/services/reports-publications/canada-communicable-disease-report-ccdr/monthly-issue/2018-44/issue-9-september-6-2018/ccdrv44i09a07-eng.pdf][71]

While the 2025 article: Montry J, *et. al.*: Post-exposure prophylaxis for the prevention of measles: A systematic review concludes with lukewarm commitment not referenced in the article's abstract[72]:

> **5. Conclusions**
>
> Our systematic review has demonstrated that the administration of measles PEP (in the form of either Ig or MCV) is likely effective at preventing confirmed cases of measles infection. However, there are several critical limitations to the available data, with poor reporting of information related to key effect modifiers, such as the time from exposure to PEP administration. Given the global importance of mitigating measles-related morbidity and mortality future interjurisdictional databases and research should seek to understand factors that impact the effectiveness of measles PEP in populations of special interest, including pregnant populations and different immunocompromised populations.,

the Cochran Database of Systematic Reviews of 2014 concluded[74]:

Authors' conclusions

Passive immunisation within seven days of exposure is effective at preventing measles, with the risk for non-immune people up to 83% less than if no treatment is given. Given an attack rate of 45 per 1000 (per the control group of the most recent included study), gamma globulin compared to no treatment has an absolute risk reduction (ARR) of 37 per 1000 and a number needed to treat to benefit (NNTB) of 27. Given an attack rate of 759 per 1000 (per the attack rate of the other included study assessing gamma globulin), the ARR of gamma globulin compared to no treatment is 629 and the NNTB is two.

It seems the dose of immunoglobulin administered impacts on effectiveness. A minimum effective dose of measles-specific antibodies could not be identified.

Passive immunisation is effective at preventing deaths from measles, reducing the risk by 76% compared to no treatment. Whether the benefits of passive immunisation vary among subgroups of non-immune exposed people could not be determined.

Due to a paucity of evidence comparing vaccine to passive immunisation, no firm conclusions can be drawn regarding relative effectiveness.

The included studies were not specifically designed to detect adverse events.

Future research should consider the effectiveness of passive immunisation for preventing measles in high-risk populations such as pregnant women, immunocompromised people and infants. Further efforts should be made to determine the minimum effective dose of measles-specific antibodies for post-exposure prophylaxis and the relative effectiveness of vaccine compared to immunoglobulin.

P L A I N L A N G U A G E S U M M A R Y

Antibodies for preventing measles after exposure

People who have had measles, or measles vaccine, have antibodies against the virus in their blood that protect them from developing measles should they come into contact with it. These antibodies can be extracted from blood donated by these individuals.

If people without antibodies come into contact with someone who is contagious with measles, they are likely to contract the disease. Measles is usually debilitating and can have serious consequences including death, so preventing it is desirable. One way of preventing measles in this group, when they do come into contact with a contagious person, is to inject them with antibodies that have been extracted from blood donations. This has been practised since the 1920s, but measures of its effectiveness have varied and the minimum amount of antibodies that we can give to prevent measles is unknown.

Based on seven studies (1432 people), of overall moderate quality, injecting antibodies into a muscle of people who came into contact with measles, but lacked their own antibodies, was effective at preventing them catching the disease compared to those who received no treatment. Using the modern day antibody preparation, people were 83% less likely to develop measles than those who were not treated. It was very effective at preventing them developing complications if they did contract measles and very effective at preventing death. The included studies generally did not intend to measure possible harms from the injections. Minor side effects were reported, such as muscle stiffness, redness around the injection site, fever and rash. Importantly, only two studies compared the measles vaccine with the antibody injection in this group of people, so no firm conclusions could be drawn about the relative effectiveness of these interventions.

> The antibody injection is often recommended for pregnant women, infants and immunocompromised people (if they do not have their own antibodies to measles and come into contact with someone who is contagious with measles). The included studies did not include these groups of people, so it is unknown whether the effectiveness of antibody injections is different for them. We were also unable to identify the minimum dose of antibodies required as only one study measured the specific amount of measles antibodies in the injections and one other study estimated this figure; the results of these two studies were not consistent.
>
> The evidence is current to August 2013.

So why have I submitted this communication to you, Fellows of the American College of Surgeons?:

Over the last five years, the agencies of the U.S. Department of Health and Human Services have been silent in their responses to my submissions.[6-13] As Fellows of the American College of Surgeons (ACS), we are all deeply-rooted in the history and traditions of the ACS.[73-78] Our pledge (Fellowship Pledge, 1986)[79] expresses our duty to U.S. Medicine and American society, to all our patients, and to ourselves:

> *Recognizing that the American College of Surgeons seeks to exemplify and develop the highest traditions of our profession, I hereby pledge myself, as a condition of Fellowship in the College, to live in strict accordance with all its principles and regulations.*
>
> ***I pledge myself to pursue the practice of surgery with scientific honesty and to place the welfare of my patients above all else; to advance constantly in knowledge; and to render willing help to my colleagues, regard their professional interest, and seek their counsel when in doubt as to my own judgment**.*
>
> *Upon my honor I hereby declare that I will not practice the division of fees, either directly or indirectly. I further promise to make my fees commensurate with the services rendered and with patient's rights.* ***Moreover, I promise to deal with each patient as I would wish to be dealt with were I in his position.***
>
> *Finally, I pledge myself to cooperate in advancing and extending the ideals and principles of the American College of Surgeons.*

Active Immunization and ***Passive Immunization*** are foundational concepts in *Clinical Immunology*. Early treatment or postexposure administration with ***Passive Immunization*** has been successfully implemented in many viral epidemics over the last ~1½ centuries when administered shortly after diagnosis.[2-4,6,8,10-13,23,31,36-44,52-73] Unfortunately, RNA viruses (e.g.: coronavirus) have a more frequent mutation rate that DNA viruses (e.g.: smallpox) thus rendering monoclonal therapy less effective than polyclonal, always-upgrading **Convalescent plasma or sera**.[80-82] Knowing the clinical usefulness of ***Passive Immunization*** when appropriately applied early (<72 hours from diagnosis) in the treatment with exogenous immunoglobulins in the daily care of the newly infected and/or exposed, immunologically-naïve individual patient to a specific virus is every physician's duty.

Could we, as *Fellows of the American College of Surgeons*, advocate throughout the literature, our institutions, and U.S. Medicine across our nation for a reaffirmation of the importance and appropriateness of ***Passive Immunization*** (administered in <72 – 96 hours after diagnosis or exposure) for immunological treatments of conditions and diseases of which our patients are clinically immunologically naïve? Could the ACS rekindle throughout the nation discussions and debates within weekly Surgery Department M&M conferences[83,84] and mirror the concept of review and oversight of *Clinical Immunology* much like the ACS's role a century ago of hospital credentialling under the direction of Dr. Codman at the national level in which the foundation of the establishment of the JACHO occurred 3 decades after the implementation of the ACS's *Hospital Standardization Program*[74,85]? In short, we as Surgeons should again assume an organized, academic, national leadership role to address misinformation and obfuscation regarding the appropriate, clinical implementation of a foundational concept of Medicine: ***Passive Immunization*** within the early (<72-96 hours from diagnosis) treatment of infectious diseases. We need to strive to correct the promotional paltering commercialism of the television and media advertisements that inundate the consciousness of the American public on a daily basis![86-95] Thank you for your consideration of this plea.

Respectfully,

Charles H. Andrus, M.D., F.A.C.S.
Retired Professor and General Surgeon, Department of Surgery, Saint Louis University SOM
Retired Attending Physician and Surgeon, Veterans Health Administration (VHA), U.S. DVA

P.S. **NIH NIAID case # 12276**

As all my submissions to the Federal Government over the last five years have been essentially ignored[6-13], I see it as my continuing duty as a federal (retired with >25 years of VHA service)[24] Physician and Surgeon of the Veterans Health Administration (VHA) of the U.S. Department of Veterans Affairs (DVA) to advocate for the American people in regards to redefining *Clinical Immunology* especially with concerns for the fundamental cornerstone theorems of Prophylaxis: ***Active Immunization*** versus Treatment: ***Passive Immunization***. Books 5[12] & 6[13], and a SDHC card containing electronically all six BOOKs, etc., and this communication will be submitted in hardcopy to Dr. Marrazzo, Director of the NIH, NIAID, who, like Dr. Fauci before her, never responded directly to my communications. (See the letter to Dr. Marrazzo of February 14, 2025, in Book 6[13] of which was never responded to by Dr. Marrazzo or any other person in the NIAID of the National Institutes of Health). By submitting Book 5[12], Book 6[13], and a SDHC card containing electronically all six BOOKs, etc., with this communication to Dr. Marrazzo, the NIH NIAID Case file #12276, all should and must be retained under federal law **ALL** within the National Institute of Allergy and Infectious Diseases (NIAID) of the U.S. National Institutes of Health (NIH) of the U.S. Department of Health and Human Services (HHS). All which has been submitted to the NIH NIAID file Case #12276 over the last five years can be requested by any person under the Freedom of Information Act for a nominal fee set by the FOIA Office of the U.S. Department of Health and Human Services, 5 U.S.C. 552 (a)(4)(a)(iii).[96,97] What is more, I will submit a hardcopy of Books 5[12] & 6[13], a SDHC card containing electronically all six

BOOKs, and this communication to *The New Journal of Medicine* requesting the addressing of the statistical incongruities of[98]:

> Korley, *et. al.*: Early convalescent plasma for high-risk outpatients with Covid-19. N Engl J Med 2021 Nov 18; 385: 1951-1960 https://www.nejm.org/doi/pdf/10.1056/NEJMoa2103784?articleTools=true
> Supplement:
> https://www.nejm.org/doi/suppl/10.1056/NEJMoa2103784/suppl_file/nejmoa2103784_appendix.pdf

of which the NIH, the FDA, and the NEJM were all involved parties.[99-101, and 30 with insight into the FDA/Mayo Clinic COVID-19 Convalescent Plasma Project] The editors of *The New Journal of Medicine* could probably ask the statisticians of several of the schools of public health across the U.S.A. to dissect, critique, and publish their statistical analyses and recommendations regarding this article and its supplement, such as: e.g., the Harvard T.H Chan School of Public Health; the Johns Hopkins Bloomberg School of Public Health; the Washington University School of Public Health, St. Louis, MO; the Saint Louis University College for Public Health and Social Justice; the University of Washington School of Public Health; the UCLA Fielding School of Public Health, etc. U.S. Medicine needs to reaffirm *Clinical Immunology* for the daily practice of medicine especially with concerns for the fundamental, cornerstone, unifying concepts of[102,103]:

Prophylaxis: ***Active Immunization*** versus Treatment ***Passive Immunization***.

All Physicians and Surgeons; Clinical, Research, and Academic Institutions; all Medical Textbooks, such as Loscalzo J, Kasper DL, Longo DL, Fauci AS, Hauser SL, Jameson JL: *Harrison's Principles of Internal Medicine*; and the American People should become knowledgeable and advocate for the reaffirmation of *Clinical Immunology*. This reaffirmation should be both in regards to the **distinctions and synergism** between the fundamental cornerstone theorems of Prophylaxis: ***Active Immunization*** versus Treatment: ***Passive Immunization***. In daily clinical practice, such a functional reaffirmation and application in the practice of medicine and surgery is consistent with and mandated by that[105,106] which Francis W. Peabody, M.D. admonished a century ago before the students of the Harvard University Medical School and should continue *ad infinitum* for all physicians for all times:

"…the secret of the care of the patient is in caring for the patient."

Respectfully,

Charles H. Andrus, M.D., F.A.C.S.

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5. Schleifer LS: Regeneron's Leonard S. Schleifer meets with Trump at the White House. https://www.youtube.com/watch?v=31i6p_stzW8 of the full 56:54 minute meeting in the Cabinet Room of The White House https://www.c-span.org/program/white-house-event/president-trump-meeting-with-pharmaceutical-executives-on-coronavirus/542511 (complete transcript: Remarks by President Trump and Members of the Coronavirus Task Force in Meeting with Pharmaceutical Companies, March 2, 2020 https://web.archive.org/web/20200303160403/https:/www.whitehouse.gov/briefings-statements/remarks-president-trump-members-coronavirus-task-force-meeting-pharmaceutical-companies/

6. Andrus CH: **BOOK 1** ***Dr Mr President.. COVID 19 And Where We Went Wrong 2023 02 02***. Internet Archive 2023-09-12, pages e1 - e1266. https://archive.org/details/book-1-dr-mr-president..-covid-19-and-where-we-went-wrong-2023-02-02

7. Andrus CH: BOOK 2 ***0 2023 09 11 Scan VA RSSO Case 286816 Letter Arrived Feb 13 2023***. Internet Archive 2023-09-11, 1 – 6 viewable files. https://archive.org/details/0-2023-09-11-scan-va-rsso-case-286816-letter-arrived-feb-13-2023/0%202023-09-11%20scan%20VA%20RSSO%20Case%20286816%20letter%20arrived%20Feb%2013%202023/

8. Andrus CH: **Book 3** ***Abridged Dear Mr President... To Care For Him Who Shall Have Borne The Battle*** **2024 02 29** Internet Archive 2024-02-29, pages e1 – e536. https://archive.org/details/book-3-abridged-dear-mr-president...-to-care-for-him-who-shall-have-borne-the-battle-2024-02-29

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10. Andrus CH: **BOOK 4** ***Biden Response To The Summary Of Book 1 COVID 19 And Where We Went Wrong***. Internet Archive 2024-02-05, pages e1 – e848. https://archive.org/details/book-4-biden-response-to-the-summary-of-book-1-covid-19-and-where-we-went-wrong

11. Andrus CH: **0.4 BOOK 4** ***Biden Response To The Summary Of Book 1 COVID 19 And Where We Went Wrong 2nd Attemp***. Internet Archive 2024-03-05, pages e1 – e848. (2nd attempt to upload due to e-pagination discrepancy in reference 5 above—but same problem when one searches BOOK 4 electronically) https://archive.org/details/0.4-book-4-biden-response-to-the-summary-of-book-1-covid-19-and-where-we-went-wrong-2nd-attemp

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13. Andrus CH: **Book 6:** ***Treatment Nihilism by the Disuse of PASSIVE IMMUNIZATION in the early treatment of postexposure and/or the early Viral Infection: e.g: COVID-19, RSV, measles (Rubeola).*** Internet Archive 2025-03-29, pages e1 – e736. ***Book-6-ltr-HSS-Secretary-Kennedy-re-passive-immunization-and-measles*** https://archive.org/details/book-6-ltr-hss-secretary-kennedy-re-passive-immunization-and-measles

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15. CMS.gov: Infectious diseases, Coronavirus Disease 2019 (2020-2023), 2020-2023 Coronavirus Disease 2019. Page 2 of 14. https://www.cms.gov/about-cms/what-we-do/emergency-response/past-emergencies/infectious-diseases

16. Azar AM: Waiver or modification of requirements under section 1135 of the Social Security Act. www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx *de facto*, I allege that the interpretation of this document became the justification of abridgement of individual American rights to *Passive Immunization* and the antiviral drug Remdesivir, guaranteed under EMTALA (the Emergency Medical Treatment and Labor Act of COBRA, Consolidated Omnibus Budget Act of 1986, PL-99-272), and the Right to Tray Act of 2018, PL-115-176. Copied verbatim:

Waiver or Modification of Requirements Under Section 1135 of the Social Security Act

March 13, 2020

1. Pursuant to Section 1135(b) of the Social Security Act (the Act) (42 U.S.C. § 1320b-5), I, Alex M. Azar II, Secretary of Health and Human Services, hereby waive or modify the following requirements of titles XVIII, XIX, and XXI of the Act and regulations thereunder, and the following requirements of Title XI of the Act, and regulations thereunder, insofar as they relate to Titles XVIII, XIX, and XXI of the Act, but in each case, only to the extent necessary, as determined by the Centers for Medicare & Medicaid Services, to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicare, Medicaid and CHIP programs and to ensure that health care providers that furnish such items and services in good faith, but are unable to comply with one or more of these requirements as a result of the consequences of the 2019 Novel Coronavirus (previously referred to as 2019-nCoV, now as COVID-19) pandemic, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse:

    a. Certain conditions of participation, certification requirements, program participation or similar requirements for individual health care providers or types of health care providers, including as applicable, a hospital or other provider of services, a physician or other health care practitioner or professional, a health care facility, or a supplier of health care items or services, and pre-approval requirements.

b. Requirements that physicians or other health care professionals hold licenses in the State in which they provide services, if they have an equivalent license from another State (and are not affirmatively barred from practice in that State or any State a part of which is included in the emergency area).

c. Sanctions under section 1867 of the Act (the Emergency Medical Treatment and Labor Act, or EMTALA) for the direction or relocation of an individual to another location to receive medical screening pursuant to an appropriate state emergency preparedness plan or for the transfer of an individual who has not been stabilized if the transfer is necessitated by the circumstances of the declared Federal public health emergency for the COVID-19 pandemic.

d. Sanctions under section 1877(g) (relating to limitations on physician referral) under such conditions and in such circumstances as the Centers for Medicare & Medicaid Services determines appropriate.

e. Limitations on payments under section 1851(i) of the Act for health care items and services furnished to individuals enrolled in a Medicare Advantage plan by health care professionals or facilities not included in the plan's network.

2. Pursuant to Section 1135(b)(7) of the Act, I hereby waive sanctions and penalties arising from noncompliance with the following provisions of the HIPAA privacy regulations: (a) the requirements to obtain a patient's agreement to speak with family members or friends or to honor a patient's request to opt out of the facility directory (as set forth in 45 C.F.R. § 164.510); (b) the requirement to distribute a notice of privacy practices (as set forth in 45 C.F.R. § 164.520); and (c) the patient's right to request privacy restrictions or confidential communications (as set forth in 45 C.F.R. § 164.522); but in each case, only with respect to hospitals in the designated geographic area that have hospital disaster protocols in operation during the time the waiver is in effect.

3. Pursuant to Section 1135(b)(5), I also hereby modify deadlines and timetables and for the performance of required activities, but only to the extent necessary, as determined by the Centers for Medicare & Medicaid Services, to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicare, Medicaid and CHIP programs and to ensure that health care providers that furnish such items and services in good faith, but are unable to comply with one or more of these requirements as a result of the COVID-19 pandemic, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse.

These waivers and modifications will become effective at 6:00 P.M. Eastern Standard Time on March 15, 2020, but will have retroactive effect to March 1, 2020, nationwide, and continue through the period described in Section 1135(e). Notwithstanding the foregoing, the waivers described in paragraph 2 above are in effect for a period of time not to exceed 72 hours from implementation of a hospital disaster protocol but not beyond the period described in Section 1135(e). The waivers described in paragraphs 1(c) and 2 above are not effective with respect to any action taken thereunder that discriminates among individuals on the basis of their source of payment or their ability to pay.
The waivers and modifications described herein apply in the geographic area covered by the President's proclamation, pursuant to the National Emergencies Act, on March 13, 2020, that the COVID-19 outbreak in the United States constitutes a national emergency; and my January 31, 2020, determination, pursuant to section 319 of the Public Health Service Act, that a public health emergency as a result confirmed cases of 2019 Novel Coronavirus, exists and has existed since January 27, 2020, nationwide.

3/13/2020 /s/

Date Alex M. Azar II

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19. President Trump signed into law PL-115-176: Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina, the RIGHT TO TRY ACT OF 2017. May 30, 2018. https://www.govinfo.gov/content/pkg/PLAW-115publ176/pdf/PLAW-115publ176.pdf

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> As the Nation's doctor, I often get asked: What should I do if I think I might have coronavirus? Well, it is important to know the symptoms--they include: fever, cough, and shortness of breath. If you are having these symptoms or worry you might have coronavirus, please call your healthcare provider. **We don't want you to go into the ER or the doctor's office without talking to them first because you might spread coronavirus to someone else.** They will help you think through and learn how to react including figuring out where to go to get tested if necessary.
>
> Dr. Jerome Adams, PSA, If You Are Sick, March 19, 2020.

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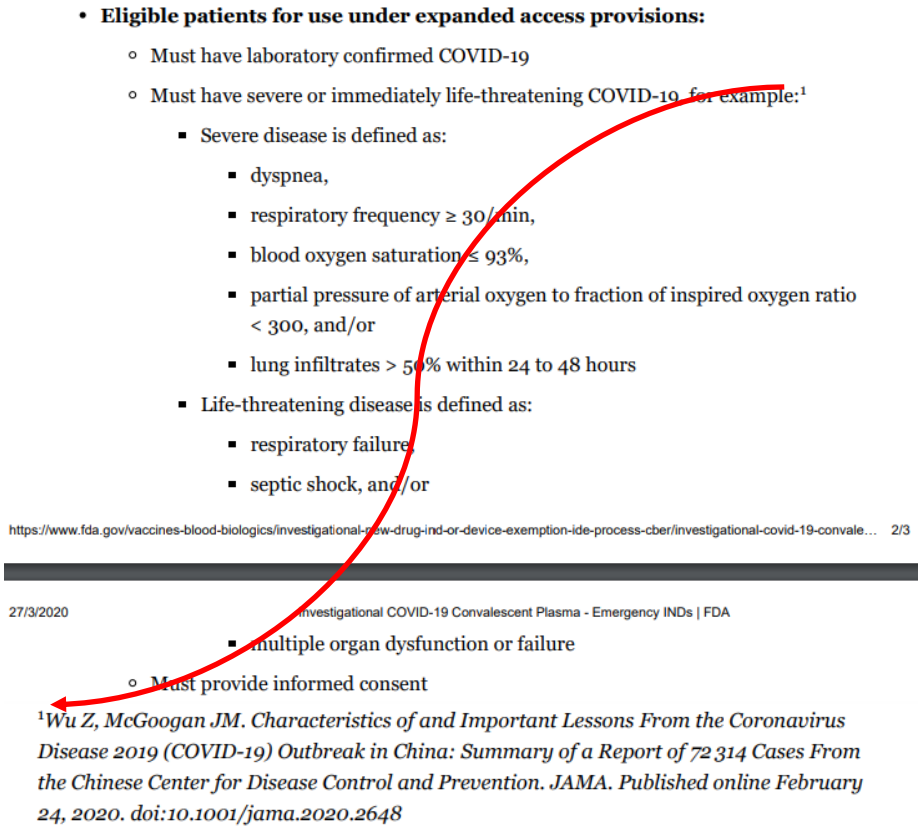

- **Eligible patients for use under expanded access provisions:**
  - Must have laboratory confirmed COVID-19
  - Must have severe or immediately life-threatening COVID-19, for example:[1]
    - Severe disease is defined as:
      - dyspnea,
      - respiratory frequency ≥ 30/min,
      - blood oxygen saturation ≤ 93%,
      - partial pressure of arterial oxygen to fraction of inspired oxygen ratio < 300, and/or
      - lung infiltrates > 50% within 24 to 48 hours
    - Life-threatening disease is defined as:
      - respiratory failure,
      - septic shock, and/or
      - multiple organ dysfunction or failure
  - Must provide informed consent

https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/investigational-covid-19-convale... 2/3

27/3/2020 Investigational COVID-19 Convalescent Plasma - Emergency INDs | FDA

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30. Joyner MJ, Paneth N, Casadevall A: Use of convalescent plasma in the treatment of COVID-19. Naturereveiws nephrology 2023 April;19: 271. **PLEASE NOTE THAT THIS IS JUST ONE CONCLUSION ARTICLE of at least *13 articles*** (see reference 13 above: pages e46 – e48 of Book 6 https://archive.org/details/book-6-ltr-hss-secretary-kennedy-re-passive-immunization-and-measles **) in which MICHAEL JOYNER, M.D., PhD**, who was the Principal Investigator for the FDA / Mayo Clinic COVID-19 Convalescent Plasma Project: www.uscovidplasma.org with other authors participating in the FDA / Mayo Clinic COVID-19 Convalescent Plasma Project wrote regarding the correct use of ***Passive Immunization*:**

> … However, this therapy must be used properly, which is to say, **early in the disease course and in the appropriate dose**. Many cited randomized controlled trials (RCTs) failed to adhere to these two treatment principles.

https://pmc.ncbi.nlm.nih.gov/articles/PMC9937736/pdf/41581_2023_Article_690.pdf

Dr. Joyner was the Principal Investigator for the FDA / Mayo Clinic COVID-19 Convalescent Plasma Project: www.uscovidplasma.org . If one goes to the ongoing overwritten URL FDA/Mayo Clinic COVID-19 Convalescent Plasma Project, **the FDA has completely devested itself from the URL** at present in the *Internet* website and its history! If one searches the Wayback Machine: https://web.archive.org/ of the Internet Archive with: https://www.uscovidplasma.org/ , the search yields https://web.archive.org/web/20250000000000*/https://www.uscovidplasma.org/ with: "Saved **1,596 times** between April 4, 2020 and March 16, 2025. An example of June 7, 2020, https://web.archive.org/web/20200607062505/https://www.uscovidplasma.org/ of the acknowledged involvement of the U.S. government was as stated:

> Responding to the unprecedented challenge of fighting coronavirus disease 2019 (COVID-19), **the U.S. Government is supporting a national Expanded Access Program** to collect

and provide convalescent plasma to patients in need across the country. Plasma from recovered COVID-19 patients contains antibodies that may help fight the disease.

Working collaboratively with industry, academic, and government partners, Mayo Clinic will serve as the lead institution for the program.

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> **...Normal Human Immunoglobulin (NHIg)**
>
> This is derived from the pooled plasma of blood donors. It contains antibodies against microbial agents that are prevalent in the general population. It provides antibodies against hepatitis A, rubella, measles and other viruses prevalent in the general population. It is most effective if it is administered within 72 hours or 3 days after exposure and provides immediate protection and will last several weeks. NHIg blocks the response of live vaccine (except for yellow fever) for 3 months. Therefore, live vaccines should ideally be given at least 3 weeks before or 3 months after administration of NHIg. NHIg is administered by intramuscular injection.
>
> Today, passive immunisation with IG still plays an important part in the prevention of measles and hepatitis A among non-immune contacts in countries with low incidences of these diseases. In some cases, passive immunisation is also recommended for non-immune pregnant contacts of rubella. …
> https://adultimmunisation.msidc.my/passive/

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Measles
Recommendations

1. For asymptomatic healthcare personnel ***with*** presumptive evidence of immunity to measles (https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6204a1.htm#Tab3)[1] who have an exposure to measles:
   - Postexposure prophylaxis is not necessary.
   - Work restrictions are not necessary.
   - Implement daily monitoring for signs and symptoms of measles from the 5th day after their first exposure through the 21st day after their last exposure.
2. For asymptomatic healthcare personnel ***without*** presumptive evidence of immunity to measles who have an exposure to measles:
   - Administer postexposure prophylaxis in accordance with CDC and ACIP recommendations (https://www.cdc.gov/acip-recs/hcp/vaccine-specific/mmr.html)[2]
   - Exclude from work from the 5th day after their first exposure through the 21st day after their last exposure, regardless of receipt of postexposure prophylaxis.
   - Work restrictions are not necessary for healthcare personnel who received the first dose of MMR vaccine prior to exposure:
     -- They should receive their second dose of MMR vaccine as soon as possible (at least 28 days after their first dose).
     -- Implement daily monitoring for signs and symptoms of measles from the 5th day after their first exposure through the 21st day after their last exposure.
3. For healthcare personnel with known or suspected measles, exclude from work for 4 days after the rash appears.
4. For immunocompromised healthcare personnel with known or suspected measles, exclude from work for the duration of their illness.
5. During a measles outbreak, administer measles vaccine to healthcare personnel in accordance with CDC and ACIP recommendations (https://www.cdc.gov/acip-recs/hcp/vaccine-specific/mmr.html).[2]

Narrative

Background …

Occupational Exposures …

Clinical Features …

Testing and Diagnosis …

Postexposure Prophylaxis
Exposed HCP without presumptive evidence of immunity should receive postexposure vaccination as soon as possible in accordance with CDC and ACIP recommendations. In some circumstances, immune globulin may be appropriate to offer these HCP, but this should be done in accordance with CDC and ACIP recommendations (https://www.cdc.gov/acip-recs/hcp/vaccine-specific/mmr.html).[2]

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    Post-exposure prophylaxis for measles
    People exposed to measles who cannot readily show that they have adequate presumptive evidence of immunity against measles should be offered post-exposure prophylaxis (PEP). Public health officials can help identify eligible persons, assess any contraindications, and weigh benefits.

    There are two types of PEP for measles. To potentially provide protection or modify the clinical course of disease among susceptible persons, administer one of these:

    - MMR vaccine, if administered within 72 hours of initial measles exposure.
    - Immunoglobulin (IG), if administered within 6 days of exposure. The recommended dose for intramuscular immunoglobulin (IMIG) is 0.5mL/kg, regardless of the contact's immune status.

    Don't administer MMR vaccine and **IG simultaneously.** This practice invalidates the vaccine.

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> **Results**
> A total of 3409 contacts were identified, of which 208 (6.1%), 274 (8.0%), and 318 (9.3%) met the inclusion criteria for analysis of MMR, IG, and any PEP effectiveness, respectively. Of the contacts included, 44 received MMR PEP and 77 received IG PEP. Effectiveness of MMR PEP was 83.4% (95% confidence interval [CI], 34.4%, 95.8%). No contact who received IG PEP developed measles; effectiveness of IG PEP was 100% (approximated 95% CI, 56.2%, 99.8%). Effectiveness of receiving any PEP (MMR or IG) was 92.9% (95% CI, 56.2%, 99.8%).

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